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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/889,936

11/19/2001

Itamar Willner

WILLNER=5

4415

1444

7590

08/25/2004

EXAMINER

YANG, NELSON C

BROWDY AND NEIMARK, P.L.L.C.

624 NINTH STREET, NW

SUITE 300

WASHINGTON, DC 20001-5303

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/889,936

Applicant(s)

WILLNER ET AL.

Examiner

Nelson Yang

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 79-140 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 79-140 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

I. Restriction is required under 35 U.S.C. 121 and 372.

1. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

2. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 79-82, drawn to a protein.

Group 2, claim(s) 83-92, drawn to an apparatus with a medium comprising first indicator agent or a second indicator agent species at a concentration in correlation to the concentration of assayed molecule in the sample.

Group 3, claim(s) 93-97, drawn to an apparatus with a sensing surface that carries residues or moieties bound to a protein molecule.

Group 4, claim(s) 98-102, drawn to an apparatus with a reagent system comprising a protein molecule.

Group 5, claim(s) 103-114, drawn to an apparatus with a sensing surface carrying capturing agents for binding to a protein molecule.

Group 6, claim(s) 115-123, drawn to a method requiring a sensing surface which carries residues or moieties bound to a protein molecule.

Group 7, claim(s) 115-123, 124-134, drawn to a method requiring contacting a sample with a protein molecule.

Group 8, claim(s) 115-123, 135-140, drawn to a method requiring a sensing surface carrying capturing agents for binding to a protein molecule.

3. The inventions listed as Groups 1-8 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

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The application contains claims to more than one of the combinations of categories of inventions as set forth by 37 CFR 1.475.

**According to 37 CFR 1.475 regarding unity of invention:**

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and a process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) above, unity of invention might not be present. Furthermore, the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art. The determination is made based on the contents of the claims as interpreted in light of

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the description and drawings. In the instant application, the products of groups 1-4 and the methods of groups 5-8 have differing special technical features:

Group 1 has the special technical feature of a protein.

Group 2 has the special technical feature of a medium comprising first indicator agent or a second indicator agent species at a concentration in correlation to the concentration of assayed molecule in the sample.

Group 3 has the special technical feature of a sensing surface that carries residues or moieties bound to a protein molecule.

Group 4 has the special technical feature of a reagent system comprising a protein molecule.

Group 5 has the special technical feature of a step requiring a sensing surface which carries residues or moieties bound to a protein molecule.

Group 6 has the special technical feature of a step requiring contacting a sample with anti-assayed molecule antibodies.

Group 7 has the special technical feature of a step requiring contacting a sample with a protein molecule.

Group 8 has the special technical feature of a step requiring a sensing surface carrying capturing agents for binding to a protein molecule.

Furthermore, the methods and products of groups 1-8 do not share a common special technical feature, as the apparatus of group 1 is known in the art as shown by Rice [US 4,314,821], who teaches a piezoelectric oscillator for performing sandwich immunoassays. Therefore the inventions do not form a general inventive concept, as they do not share a common special technical feature.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

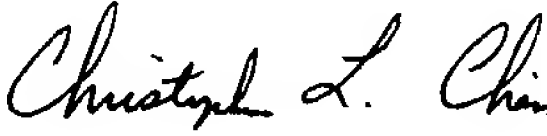
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826.

The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

6. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang  
Patent Examiner  
Art Unit 1641

  
CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800/1641  
8/22/08